REMARKS

Claims 1,10,13, and 17 are amended and pending in the application

Claims 1-20 are now pending in the application. ~~Claims 1, 3,10, 13, and 17 have been amended~~. They now reflect that the cuff directs the passage of blood only from inlet to outflow catheter and the purified blood is directly deposited into the right atrium.

Also the term silicone in claim 10 has been replaced with biocompatible material.

Drawings:

Fig 1. The drawing remains the same. The cylindrical cuff (13) made of biocompatible material which encircles the venous outflow catheter (11) and is surgically anastamosed to the arterial inflow graft (12). The venous outflow catheter has a diameter 1mm smaller than the arterial graft. The cuff directs the passage of blood from the arterial graft to the venous outflow catheter. The cuff ~~defines a graded interior diameter to provide~~ provides a secure fit for both the arterial graft and the venous outflow catheter. Figure 2 and 3 will remain the same as previous.

RESPONSES

Let us please look carefully at the basis of the claims rejections to see why there is no basis for any of the rejections. The quotation of 35 U.S.C. 103(a) "which form the basis for all obviousness rejections set forth in the office action" as the examiner states. It relies exclusively on the fact that the examiner can comprehend what ordinary skill in the art he or she is examining is. From viewing all the communications these examiners have written it is clear that they do not know what ordinary skill in this art is and will not. A person with ordinary skill in this art is someone who is allowed to actually use such a devices to perform the life saving procedures at critical times when a patient needs it. It requires that the person with this ordinary skill has dissected the structures and on a human body and studied the organs and vascular structures to the highest degree as taught in United States medical schools. It would require that person with such "ordinary skill" to excel in medical school to be selected for training which few of the graduates can attain. It would require that person be allowed to perform these procedures on live patients, where one is attempting to access and operate on the vascular system in an emergent manner. It could be placing a central venous line emergently, placing a dialysis catheter emergently, or surgically placing an arteriovenous shunt in the operating room. This would require to person of

"ordinary skill" to be selected for emergency medicine or vascular surgery training. It would require this person of "ordinary skill" to perform at a high level for 110-130 hrs/wk to be allowed the privilege to handle these devices at critical times to save patients lives. To still perform these tasks in the middle of the night, even though you have been awake for 40hrs. There is no substitute for actually having the experience, skill and medical knowledge which comes from over 11 years of the most intensive medical training a person can experience. Leslie Deak cannot learn these things by simply reading about what other people's patents are on paper. The examiner cannot hyperspace into this position and give an opinion on what "ordinary skill" in this art when he has absolutely no comprehension of what that person's knowledge and skill level is. It is impossible.

It negates the basis for all of her rejections because in no way can she understand what ordinary skill in this art even is, at his current level of education and training. One cannot go from zero medical training to understanding the limitations, functions and nuances of medical devices and procedures that it takes some with "ordinary skill" in the art over 11 years of intensive medical training to achieve.

If need be, based on the result of this appeal, I am very willing to take matter the matter to federal court where the examiners can state explicitly how they achieved understanding of "ordinary skill" in this art to render an opinion on what a person with "ordinary skill" would be able to develop based on their cited previous art. I will also try this matter, in civil court, to reclaim lost time

and wages regarding dealing with the examiners in this case.

I cannot render opinions on what ordinary skill in the art of designing new O rings on the space shuttle. I have no training or education in aerospace engineering. It would ridiculous. These examiners have no graduate medical training or even basic anatomical training one would receive in medical school. They cannot render any opinion on what ordinary skill in this art is until they achieve that level of knowledge and procedural skill with regarding these devices which comes as mentioned with over 11 years of medical and surgical training and education.

An undergraduate biology, which Ms. Deak has , in no way gives her the knowledge or skill to makes judgments on what someone with "ordinary skill" in the art vascular surgery, emergency medicine and invasive vascular devices can and cannot come up with in light seeing . A vascular surgeon (As co-inventor Dr. Nazir Khan is) who studies, trains, and operates for 11yrs, after attaining his undergraduate biology degree, has obviously a skill and knowledge of vascular devices and the vascular anatomy and disease pathology which is impossible to attain with just an undergraduate biology degree. If the inventors did not have to waste so much of their time with this process, not realizing these examiners have no expertise in the field they are examining, it would be comical.

The other sad part of this examination is related to the fact that two legal sensitive communications regarding this patent were sent to the wrong

person, who could view official communications when they had no legal right to do so! The public deserves better than this incompetence. The email record sent to Ms. Deak and Director Schmidt regarding this gross mishandling of sensitive records are presented separately at the end of this communication in addendum 1, for the appeal board to review. Director Schmidt intervened to get the communication to me in the mail and I thank him again.

I present for the appeals board why I, Dr. Iftikhar Khan, have ordinary skill in this art. I graduated at the top of my medical school class from a United States medical school. I was selected to the medical honor society. I scored a 99% on my US medical licensing exam, one of the most difficult professional licensing exams in the world. I served as the chief of my residency. I was selected to surgical and emergency medicine training programs at two of the top hospitals in our nation. I practice this art every day of my life. I have studied this art at the highest level through 10 yrs of graduate medical training and now practical experience as an attending physician in some of the top hospitals in the world.

I can estimate what ordinary skill in this art as well as extraordinary skill: What did I know about ordinary skill in this art after obtaining an undergraduate degree in biology(nothing). What did I know about ordinary skill in this art after obtaining a Doctor of Medicine degree? (at least something, but not ordinary skill) I covered the physiology and anatomy of the human body with rigorous detail and was able to assist physicians in implanting these devices in live patients in the operating room. What did I

know about ordinary skill in this art after training for 6 years in the intensive care unit, emergency department, and operating room actually handling and using the devices to save critically ill patients? (ordinary skill in the art). What do I know now that I am board certified by the American Board of Emergency Medicine and now selected as a fellow of the American College of Emergency Physicians (more than ordinary skill in the art). It is a difficult, highly selective process that takes 11 yrs after starting medical school.

Ms. Deak cannot speculate about what ordinary skill in this art is and what a person with ordinary skill in the art might be able to develop or not, when she herself has zero skill, knowledge or actual training in this art. I welcome her to try to start the process. The basis for all of her rejections is therefore invalid and the rejections should be all removed. It has all been a house of cards- I wish I had recognized it earlier.

I am very serious about this next point. I will try the matter in federal court, and Ms. Deak can discuss how exactly she has ordinary skill in the art. I will also recover immense lost time and wages in civil court against these examiners and for what has been stated above and the reasons below.

My patent attorney and many others have said, the goal is for the examiner to prolong this as long as possible, almost always issuing a final rejections and charging more fees. This process is determined to exhaust the individual inventor until they just give up or are bankrupt. I never give up.

Response to Specific Rejections

Response to Rejections of claims 1-5,7-10,12-14,17, and 18 under 35 USC. 103(a) as being unpatenable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

1. Rejections under 37CFR 1.83(a)

The cuff which connects the arterial graft to the venous outflow catheter covers the outside of the venous outflow catheter as shown in Fig. 1 of the application. The conduits have varying diameter and the cuff provides a secure fit for arterial graft and venous outflow catheter. The diameter of the cuff and venous outflow catheter equals the diameter of the arterial inflow graft, as shown in fig1. The cuff is surgically anastamosed to the arterial graft (arrow 12, Fig.1). The examiner fails to understand that the cuff does not have a "sloping" or "graded" inside diameter. It connects the catheter and the graft of varying diameters. Therefore, the objection under 37 CFR 1.83(a) should be withdrawn.

Response to Claim Rejections -35 USC 103

In response to rejections of claims 1-5,7-10,12-14,17, and 18 are rejected under35 U.S.C 103(a)

In arterio-venous shunts the blood flows through the shunt which is connected to the artery and the vein. The blood flows at arterial pressures and the blood is taken out from the graft and returned to the venous side after purification from the dialysis machine (*History of vascular access for haemodialysis.* Konner K.Nephrol Dial Transplant. 2005 Dec;20(12):2629-35. Epub 2005 Oct 4).

The brachio-axillary shunt utilizing a PTFE graft was first used in 1976 (H.B Bittner et al, Am Journal of Surgery 167:615,1994) Eighty percent of the grafts fail because of narrowing at the venous anastomosis side due to neo-intimal hyperplasia. Doctors are developing methods to avoid this neo-intimal hyperplasia. In that regard, Squitieri et. al. developed a hemodialysis shunt with no venous anastomosis, putting the venous catheter directly into a large vein-See Fig 6, arrow 42 and page 6, column 65; also column 3 FIG 7. In Squitieri's invention, the metallic connector connects the venous outflow catheter and the arterial graft with no surgical anastomosis (refer to Fig 7 and 8, Squitieri et al, U.S 6,582,409 B1.

In Parks et al US 5,399,173 the connector joins the conduits with graded interior wall regions to direct the fluids into the stomach. This is a gastrostomy tube for the purpose of feeding the stomach and has no relationship with our art or any other vascular device. Someone with ordinary skill in this art can in no way look at a gastrostomy tube in light of Squiteiri's device and somehow have the magical idea of creating our device. No one with ordinary skill in this art could do that and the inventors for the numerous reasons regarding education and training as stated, can comprehend what "ordinary skill" in this art is and the examiner cannot. The examiner does not understand the basic differences between a gastrostomy feeding tube and an arteriovenous shunt. This is because she has no knowledge in this art and as noted before, and is speculating what ordinary skill in this art is.

In our art, the venous outflow catheter is positioned in the right atrium and not in the vein. Squitieri's patent was based on the positioning of the venous outflow catheter in the vein. Our art is different as we do not position the catheter in the vein. We position our catheter in the right atrium so that the blood is directly deposited into the right atrium. In addition, Squitieri does not mention the name of the vein that he puts the catheter in. This is acknowledged by the examiner that Squitieri does not mention any name of any vein. We do not know which vein Squitieri's catheter is even in, so how can the examiner say he catheter is capable of migration to anywhere. Any reference to a change

of the position of Squitieri's outflow catheter from the vein to any other position outside the vein shall lead to invalidation of his patent. Therefore, the rejection of the claims 1-5,7-10,12-14,17 and 18 should be respectfully withdrawn

Response to rejections of claims USC 103 6,11,15,16,19,20.

In Squiteiri's device there is no mention of the name of the veins or the particular arteries that the shunt is connected to. Teretola et.al US 5,591,226 discloses a stented graft, Fig 9a, connecting the brachial artery to the axillary vein Fig 9a. This is a brachio-axillary shunt and the graft is inserted into the artery and the vein without anastamosis.

This art is different from ours because in our invention the venous outflow catheter is not placed in the vein. The cuff in our art connects the conduits of varying diameter. With regard to Parks art, as mentioned before Parks' invention is a non-analogous art which is not in the field of the applicant's endeavor. Ours is an arteriovenous shunt for dialysis. Parks device is a feeding gastrostomy tube which is inserted into the stomach. Also the cuff in Parks' invention cannot be transferred or used in our invention. A person of ordinary skill in vascular surgery or vascular devices could in no way look at a gastrostomy tube in light of Squitieri's invention and Teretolas invention and magically conceive of our invention. This is nonsense. There the rejections 6,11,15,16,19 and 20 under USC 103 should be withdrawn.

Response for rejection to claim 10. The claims have been modified using a biocompatible material in place of polyurethane. Therefore the rejection should be withdrawn. With regard to the claim 17, the rejection, Squitieri describes the hemodialysis apparatus connecting artery with a graft and a catheter for insertion into the vein without mentioning the name of the arteries and names of the vein.

With regards to Twardoski et al US 5,509,897. Twardoski's invention is a hemodialyis catheter in which the distal end of the catheter remains in the vein. This is not an arteriovenous shunt where the blood flows continuously at high arterial pressures. In his art the blood is withdrawn at the time of dialysis through one lumen and returned back after purification to the other lumen. At other times there is no flow of blood through the catheter. Therefore the combine references of Squitieri, Parks, and Twardoski do not match the present art, therefore the rejection of claims 17 under 35 USC should be withdrawn.

It appears that the combined references of Teratola et al (1997) and Twadorski (1996) appears to match Squitieri's art of 2003 very closely. The prior art is in the veins as described and Squitieri's catheter is in the vein. Squiteiri's invention became patentable despite these similarities with Teratola and Twardoski. There is no justification to deny our invention based on the arguments presented by the examiner when they were not even applied to Squitieri's invention and his device became patented.

CONCLUSION

Applicants submit their full and complete response to the Appeals Board .

A favorable consideration is respectfully requested. Thank You.

Dated 1/25/09

Iftikhar Khan MD

Nazir Khan MD

747 W Wrightwood Ave , Unit C
Chicago IL 60614

Addendum 1: regarding email communications

Issues with patent examination with Leslie Deak

Thursday, July 31, 2008 3:46 PM
From:
"Iftikhar Khan" <mds082003@yahoo.com>
View contact details
To:
"frederick schmidt" <frederick.schmidt@uspto.gov

Dear Mr Schmidt,

I am writing to you because Examiner Leslie Deak has handled the patent examination serial number **10/812380 Hybrid Arteriovenous Shunt**

very poorly. She has sent the patent communications to the wrong address not once but twice. Sending a sensitive document to the wrong address once is bad, but sending it again to the wrong address after myself and the attorney called her to tell her that the correspondence has changed is not competent work. These are important documents regarding the examination of a patent and to send them to the wrong address is serious.

Where did the first mailing of the patent response go to?

Saturday, September 13, 2008 1:04 PM
From:
"Iftikhar Khan" <mds082003@yahoo.com>
View contact details
To:
"frederick schmidt" <frederick.schmidt@uspto.gov>
Cc:
Tatyana.Zalukaeva@USPTO.GOV
Dear Director Schmidt,

Thank you again for intervening. I finally received the response from Ms. Deak in the mail. Two times, as you know the correspondence was sent to a party which had no right to access the response, but even more shocking is that she said one copy was incorrectly mailed to the wrong address. Really? Well what address was it sent to so I could tell that person to destroy the copy that he or she received months before I did. If there is an address it should be documented somewhere, since sensitive documents are being sent to

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Addendum 1: regarding email communications

incorrect addresses. This whole examination has been extremely poor and if I have to take these examiners to federal court to win this patent, that will be fine since there are so to take these examiners to federal court to win this patent, that will be fine since there are so many legitimate factors to discuss on how bad a job they have done which should be revealed to many.

Thank you

Dr. Khan

Fw: RE: email patent release

Tuesday, September 2, 2008 7:35 PM
From:
"Iftikhar Khan" <mds082003@yahoo.com>
View contact details
To:
"leslie deak" <Leslie.deak@uspto.gov>
Cc:
"fred schmidt" <frederickschmidt@uspto.gov>, "nazir Khan" <nazirkhanmd2003@yahoo.com>
Ms. Deak,

The release with the slashes is below. Since you originally told me it could be sent via email and now you say it cannot, then send it via the US mail with a current date that reflects that it has never arrived to me. These previous rejections were sent to Harness, Dickey and Pierce **via email** including the most recent rejection; so how exactly did they receive these communications via email before, twice no less, when they should not be legally seeing any of the communications, and now you say you are not supposed to email final rejections? You are contradicting what you have done again.

Your statements again do not explain how these sensitive communications, which were not ever supposed to be viewed by Harness, Dickey and Pierce, were sent to them twice. I have all the emails saved which documents that they contacted you the first time it happened and somehow you emailed them the final rejection, (which now you are saying cannot be emailed) **but nonetheless you emailed it.** **Of course they are not even supposed to see it, but now you are telling me that you cannot email it to me, yet you emailed it to them.**

Addendum 1: regarding email communications

This defies reason, is inexcusable, and the public deserves better than this.

The only reason it is coming to me now is because I have had to keep calling you to send it.

Can you please send the Office action finally to my address in the US mail with a current date. Please do not send it anywhere else.

I'm very happy Mr. Schmidt is aware of these problems because someone with authority at the USPTO needs to be. He will be cc'd on all communications with you.

You have never provided any help before, yet in this email you seem to provide so much information. I found the MPEP guide on my own after asking you where it was by email and phone with no response.

Best regards to you as well

Thank You